

REMARKS

In the Office Action, claims 28-32 are rejected under 35 U.S.C. §102 in view of U.S. Patent No. 5,252,595 (Gluchowski). As previously provided, claims 28-32 have been canceled without prejudice or disclaimer, and thus, the rejection has been rendered moot and should be withdrawn in view of same.

Further, Applicant has added new claims 33-36. Claim 33 recites an ophthalmic formulation including a sterile aqueous carrier; and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. Claims 34-36 depend from claim 33. Applicant believes that new claims 33-36 should be considered patentable over Gluchowski.

The primary emphasis of the Gluchowski formulation is directed to reducing or maintaining intraocular pressure in animals of the mammalian species. See, Gluchowski, col. 1, lines 26-29. In Gluchowski, “[t]he primary effect on the mammal resulting from the direct administering of the active compound or compounds to the mammal's eye is preferably a reduction in intraocular pressure.” See, Gluchowski, col. 4, lines 34-38.

In contrast, the claimed invention is directed to an ophthalmic formulation with an active phentolamine compound that can effectively reduce pupil size in dim light to improve vision in dim light and further minimize redness in the eye upon use. Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, Published Specification (US2004/0176408), Examples 1 and 2 and Tables 1 and 2, beginning on page 6. Indeed, practitioners in the art at the time of filing generally recognized that reducing pupil size in dim light would worsen vision.

At best, Gluchowski indicates that oxazoline or imidazoline compounds are preferred (See, Gluchowski, col. 3, lines 39-41), but nowhere does Gluchowski specify an ophthalmic formulation that includes a pharmaceutically active compound consisting essentially of phentolamine and in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness as required by the claimed invention. Again, Gluchowski is directed to

intraocular pressure and not reduction in pupil size, let alone the reduction of pupil size in dim light to improve vision in dim light where redness is further minimized as required by the claimed invention. Therefore, Applicant believes that claims 33-36 should be considered patentable for at least the reasons as discussed above.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

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